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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,456	09/30/2003	Ralph N. Martins	520531-2001	5975

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EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,456	MARTINS, RALPH N.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-25, and 40 drawn to a method of identifying peptides that bind to agents that have SOD activity, such as Abeta which is bound to copper ion, classified in class 435, subclass 7.2.

   II. Claims 26-39, 45 drawn to the product identified and polynucleotide encoding it, classified in class 514, subclass 2.

   III. Claims 41-44, drawn to a method of inhibiting SOD activity by administering the peptide of group II, classified in class 514, subclass 2.

   IV. Claim 46, drawn to a method of identifying peptides that bind to a zinc binding agent, classified in class 435, subclass 7.2.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to identify peptides that bind specifically to another protein, such as the NMDA receptor.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of group III can be practiced with a peptide identified in an assay to identify peptides that bind the NMDA receptor.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons:

Groups I and III are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention group I is a method of identifying a peptide product and group III is a method of inhibiting activity comprising contacting a causative agent with a peptide product. Each method can be used to either identify peptides or contact causative agents that are unrelated to the instant product(s), and are therefor not required each for the other. Therefore a search and examination of the methods of group II and group VI would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Groups I and IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention group I is a method of identifying a peptide product and group IV is a method of identifying an unrelated peptide product. Group I is directed to identifying peptide products that inhibit SOD

activity, and further inhibit SOD activity by interfering with a copper binding site, which is present in Abeta. Group IV is directed to identifying peptide products that bind a zinc binding site of Abeta, which not the same site as the site wherein copper binds and does not generate SOD activity. Therefore a search and examination of the methods of group I and group IV would constitute an undue burden, since the searches are different and not coextensive, and the subject matter divergent and not overlapping.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons:

Groups III and IV are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention group III is a method of inhibiting activity comprising contacting a causative agent with a peptide product of performing the method of group I, whereas group IV is an unrelated method of identifying peptides. Neither one requires the other, and one cannot use the method of group IV to obtain a product for use in the method of group III. Therefore a search and examination of the methods of group III and group IV would constitute an undue burden, since the searches are entirely different and not coextensive and the subject matter divergent.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the

different inventions are a product and a method that are unreated. Group II is to a product that is derived from a different method than the method of group IV. Group IV is directed to a method of finding peptides that bind a zinc site on A-beta, whereas the product of group II is derived form a method of finding peptides that inhibit SOD activity, which is unrelated to zinc.

Species Election

Should applicant choose group II, a further restriction is required. This application contains claims directed to the following patentably distinct species: SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 (claim 27), a peptide that binds at or near the copper binding site and physically prevents copper from binding (claim 28), a peptide that binds at or near amino acid 13 of Abeta (claims 29-31), a peptide that disrupts the conformation of the copper binding site to reduce or totally remove its ability to bind copper (claims 32-35), a peptide that binds to Abeta and reduces or totally removes its SOD activity whilst still allowing the Abeta to bind copper (claim 36), a peptidomimetic (claim 38). Therefore the species are independent and distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 'a peptide identified by the method of claims 1-3 [of claim 26]' is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In Re Ochia

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
4/06/06

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER